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TOWNSEND and TOWNSEND and CREW LLP

By: Joy A. Roeder
Joy A. Roeder

PATENT
Attorney Docket No. 021770-000120US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re application of: | Confirmation No. 8217 |
| EITAN KONSTANTINO | Examiner: NGUYEN, VI X |
| Application No.: 10/810,330 | Technology Center/Art Unit: 3731 |
| Filed: March 25, 2004 | APPELLANTS' BRIEF UNDER 37 CFR §41.37 |
| For: APPARATUS AND METHODS FOR TREATING HARDENED VASCULAR LESIONS | |

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Commissioner:

Further to the Notice of Appeal mailed on April 9, 2010 for the above-referenced application, Appellants submit this Brief on Appeal.

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**1. Real Party In Interest**

All right, title and interest in the subject invention and application was assigned to AngioScore Inc., having offices at 5055 Brandin Court, Fremont, CA 94538. Therefore, AngioScore Inc. is the Real Party in Interest.

**2. Related Appeals And Interferences**

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

**3. Status Of Claims**

Claims 60-64, 69 and 70 are currently pending. Claims 1-59 and 65-68 have been previously canceled. Claims 60-62, 64, 69 and 70 were rejected under 35 U.S.C. 102(b). Claims 60-64, 69 and 70 were rejected under 35 U.S.C. 103(a). Claims 60-64, 69 and 70 are the subject of this appeal. No other claims are pending.

**4. Status Of Amendments**

No amendments to the claims were filed subsequent to the Final Office Action mailed on March 19, 2010 (Final Office Action). No responses of any kind were filed in response to the Final Office Action. A copy of all pending claims which are the subject of the appeal is provided in the Claims Appendix, attached hereto.

**5. Summary Of Claimed Subject Matter**

The present invention provides methods for delivering a drug to a blood vessel lesion (page 1, lines 11-13) by inflating a balloon to expand a scoring structure (page 7, lines 15-23), scoring the stenotic material with a balloon catheter having a scoring structure comprising metal scoring elements (page 5, lines 6-18; page 16, lines 20-23) and delivering a drug to the scored lesion (page 17, lines 14-18). By penetrating the stenotic material with the scoring elements of the scoring structure, the described methods allow for better diffusion of the drug through the lesion and enhance delivery of the drug to the vessel wall (page 17, lines 10-15).

Independent claim 60 and dependent claims 61-64 and 69-70 are directed to these methods. Unless otherwise noted, all page and line numbers herein refer to the original text of Application No. 10/810,330, as filed on March 25, 2004.

Independent claim 60 is directed to a method for delivering a drug to a blood vessel lesion (page 17, lines 10-18) comprising inflating a balloon to radially expand a scoring structure to radially penetrate stenotic material (page 5, lines 6-10; page 18, lines 18-23) and releasing a drug into the scored lesion to enhance delivery into the vessel wall (page 17, lines 10-15). The scoring structure of claim 60 comprises metal scoring elements carried by the balloon (page 5, lines 9-14; page 9, lines 12-16; page 17, lines 19-24) wherein balloon inflation engages the scoring elements against stenotic material in the lesion to radially penetrate the stenotic material (page 7, lines 18-23).

Dependent claim 61 recites the method as in claim 60 where the drug is carried by the balloon as a platform (page 17, lines 14-15).

Dependent claim 62 recites the method as in claim 60 where releasing comprises embedding the drug through the stenotic material into the vessel wall (page 17, lines 16-18).

Dependent claim 63 recites the method as in claim 62 where the drug is present in capsules (page 17, lines 16-18).

Dependent claim 64 recites the method as in claim 62 where the drug is present in a drug-containing polymer (page 17, lines 16-18).

Dependent claim 69 recites the method as in claim 60 where the metal scoring elements are included in a scoring cage slidably carried to the expansible balloon (Abstract; page 9, lines 12-15, Figs. 2 and 6).

Dependent claim 70 recites the method as in claim 60 where the scoring elements in the scoring cage are arranged helically over the expansible balloon (page 9, lines 23-28).

**6. Grounds Of Rejection To Be Reviewed On Appeal**

Whether claims 60-62, 64 and 69-70 were properly rejected under 35 U.S.C. 102(b) as being anticipated by March et al. (US 5,306,250).

Whether claim 63 was properly rejected under 35 U.S.C. 103(a) as being unpatentable over March et al. (US 5,306,250).

Whether claims 60-64 and 69-70 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Ruiz (US 5,868,779) in view of Dror et al. (US 5,102,402).

**7. Argument**

Rejections Under 35 U.S.C. § 102(b)

Claims 60-62, 64 and 69-70 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 5,306,250 to March et al. (hereinafter "March"). Appellants believe that the Examiner has not established anticipation, and therefore respectfully traverses these rejections for the following reasons.

A single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. § 102; M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that "the identical invention must be shown in as complete detail as is contained in the . . . claims." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). March fails to disclose each and every element of the rejected claims.

Independent claim 60 reads as follows:

> *60. A method for delivering a drug to a blood vessel lesion, said method comprising:*
>
> *inflating a balloon to radially expand a scoring structure comprising metal scoring elements carried by said balloon, wherein the balloon inflation engages the scoring elements against stenotic material in the lesion to radially penetrate the stenotic material; and*
>
> *releasing a drug into the scored lesion to enhance delivery into the vessel wall.*

Independent claim 60 requires "inflating a balloon" to radially expand a "scoring structure comprising metal scoring elements" which "engages the scoring elements against stenotic material . . . to radially penetrate the stenotic material." As shown below in Figure 17a of the present application, the external scoring structure 252 is carried over the balloon and expanded by inflation of the balloon 254 (page 5, lines 6-26).

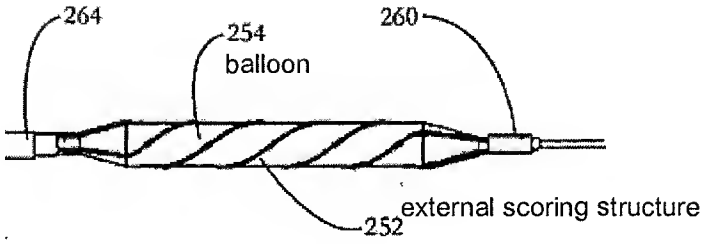



Fig. 17a

The March patent teaches a drug delivery catheter that uses an exoskeleton frame or cage to expand a porous membrane then forces a drug through the membrane (March, col. 3, lines 34-38). The cage 54 comprises spirally arranged wires 56 "in contact with the inner surface 47 of membrane 46" (col. 6, lines 1-13) that expand the porous membrane from within in response to rotation of a cap 36 (col. 6, lines 13-37). Once the membrane is expanded, a drug containing liquid is released through apertures 48 in the porous membrane (col. 6, lines 37-49).

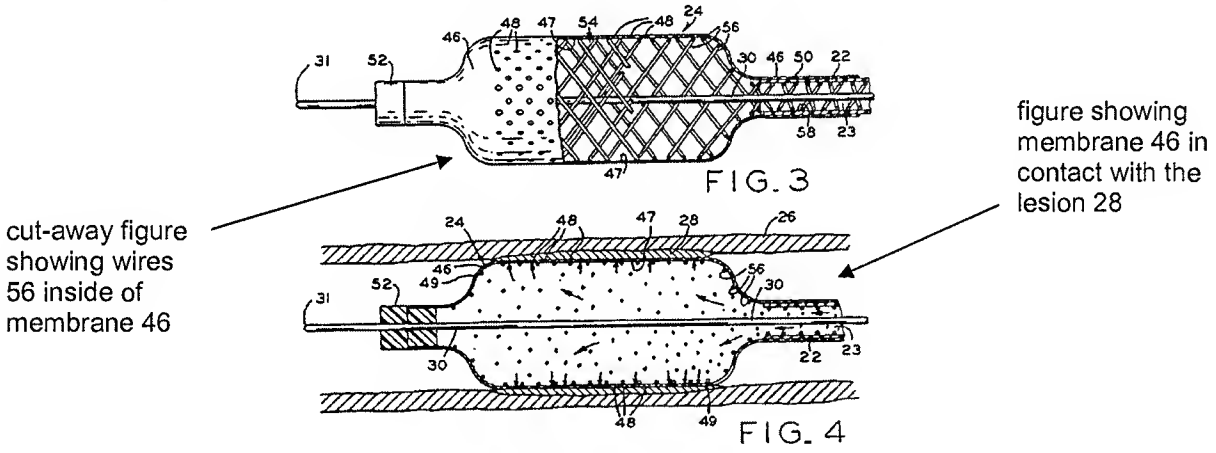



FIG. 3

FIG. 4

March plainly fails to teach either a scoring structure or inflating a balloon to expand a scoring structure. Although the Examiner argues that March teaches a "scoring element 56 that can either engage or penetrate stenotic material" (Final Office Action, page 4), Applicants disagree. The wires 56 of the cage in March are incapable of either engaging or penetrating stenotic material because they lie beneath the membrane 46 (col. 6, lines 11-15). To locate the wires elsewhere would render the device useless for its intended purpose since the wires expand to engage the membrane 46 against the lesion 28 (col. 6, lines 39-41). Figures 3 and 4 of March (shown above) clearly illustrate the wires 56 within the membrane 46. March also fails to teach inflating a balloon to expand a structure. The porous membrane 46 in March is

expanded by the expanding cage 54, not vice versa. Additionally, the membrane cannot possibly be considered an inflatable balloon because the fluid introduced into the membrane simply flows out through apertures in the membrane. Thus, March fails to teach all the elements of claim 60 and all claims depending therefrom, and the rejections under § 102(b) should be reversed.

Rejections under 35 U.S.C. § 103(a)

The rejection of claim 63 under 35 U.S.C. § 103(a) as being obvious over March should be reversed. Appellants believe that the Examiner has not established *prima facie* obviousness under 35 U.S.C. § 103(a) and MPEP §§ 2142 and 2143, and therefore respectfully traverse these rejections for the reasons discussed below.

The Examiner bears the initial burden of establishing *prima facie* obviousness. MPEP § 2142. A finding of *prima facie* obviousness requires ascertaining the scope and contents of the cited references and ascertaining the differences between the cited references and the claims at issue, as well as the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. 1, 148 U.S.P.Q. 459 (1966) and KSR International Co. v. Teleflex No. Inc., 550 U.S. 398; 82 U.S.P.Q. 2nd, 1385 (2007).

The basic factual inquiries of Graham as affirmed by KSR require the following:

(A) determining the scope and content of the prior art;

(B) ascertaining the differences between the claimed invention and the prior art; and

(C) resolving the level of ordinary skill in the pertinent art.

Once the Graham factual inquiries are resolved, it is the Examiner's burden to articulate "a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference." MPEP § 2143(A). The Examiner has not met this burden with respect to the rejected claim.

Regarding the rejection of claim 63, the Examiner argues that March discloses the invention "substantially as claimed" and relies on the general skill of a worker in the art to include a drug present in capsules (Final Office Action, page 3). Applicants disagree.

Regardless of whether incorporating a drug present in capsules would be an obvious variation of March's teachings, March fails to disclose the fundamental steps of independent claim 60. Thus, claim 63, which depends from claim 60, cannot be considered obvious.

Accordingly, the rejection of claim 63 under 35 U.S.C. § 103(a) over March should be reversed and the claims allowed.

Claims 60-64 and 69-70 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,868,779 to Ruiz (hereinafter "Ruiz") in view of U.S. Patent No. 5,102,402 to Dror et al. (hereinafter "Dror"). Appellants believe that the Examiner has not established *prima facie* obviousness, and therefore respectfully traverse these rejections for the following reasons.

Ruiz and Dror fail to teach a scoring structure comprising metal scoring elements that engage and radially penetrate stenotic material, as in claim 60. Ruiz is directed to a balloon catheter constrained by a non-compliant mesh that expands to a predetermined diameter (Ruiz, Abstract; col. 3, 47-63). By covering the balloon element, the mesh allows the use of higher inflation pressures and prevents bulging of the balloon member, rupture of the balloon and dissection of the vessel (col. 3, lines 1-20). The mesh taught in Ruiz, shown in Figure 3, must adequately constrain and equalize stresses around the balloon surface (col. 4, lines 50-61).

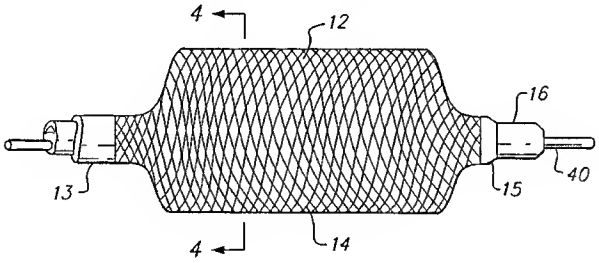



*FIG. 3* (Ruiz)

In contrast to Ruiz, the claimed method expands a balloon which engages metal scoring elements against stenotic material to penetrate the stenotic material. As shown in Figure 17a of the present application, the scoring structure ideally has a reduced vessel contact area, which increases the amount of force from the expanding balloon promoting scoring of the stenotic material to radially penetrate the stenotic material (page 7, lines 12-30). The mesh of Ruiz is designed to constrain the balloon, equalize stresses and prevent perforation or dissection

of the vessel, which teaches against penetrating the stenotic material. Hence, the mesh of Ruiz is distinguishable from the claimed method and Ruiz fails to teach all elements of claim 60.

The Examiner relies on Dror as teaching releasing a drug into a scored lesion. Dror is directed to methods and apparatus for delivering a drug by expanding a drug coated balloon. Applicants concede that Dror teaches releasing a drug into a vessel wall, however, the question is whether there would be a reason to combine Dror and Ruiz. Additionally, Dror fails to teach the elements of claim 60 missing from Ruiz. Thus, the Examiner has not established *prima facie* obviousness having failed to disclose all the elements of claim 60 and a reason to combine Dror and Ruiz.

Rejected claims 61-64 and 69-70, which depend from claim 60, are also distinguished from Ruiz and Dror for at least reasons similar to claim 60.

For the foregoing reasons, Appellants respectfully submit that a *prima facie* case of obviousness has not been met because the Examiner's rejection under Ruiz and Dror fail to satisfy the threshold requirement that the cited references teach or suggest all elements of the claimed invention.

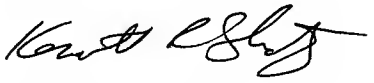
Accordingly, the rejection of claims 60-64 and 69-70 under 35 U.S.C. § 103(a) over March in view of Dror should be reversed and the claims allowed.

Regarding the rejection of claims 60-64 and 69-70, the Examiner, having fully considered the Applicant's December 7, 2009 response, stated that the "applicants failed to point out any argument regarding" the rejections and that "it is taken as admission that the above rejections can still sustain . . . " (Final Office Action, page 4). Applicants note, however, there has been no admission as the response clearly stated: "as neither of the secondary references teach or suggest inflating a balloon in order to engage metal scoring elements against stenotic material, it is believed that independent claim 60 as well as all claims dependent thereon distinguish the cited art and are in condition for allowance."

**8. Conclusion**

For these reasons, it is respectfully submitted that the rejections should be reversed.

Respectfully submitted,



Kenneth R. Shurtz
Reg. No. 66,184

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 650-326-2400
Fax: 650-326-2422

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**9. Claims Appendix**

1. - 59. (Canceled)

60. (Previously Presented) A method for delivering a drug to a blood vessel lesion, said method comprising:

inflating a balloon to radially expand a scoring structure comprising metal scoring elements carried by said balloon, wherein the balloon inflation engages the scoring elements against stenotic material in the lesion to radially penetrate the stenotic material; and

releasing a drug into the scored lesion to enhance delivery into the vessel wall.

61. (Previously Presented) A method as in claim 60, wherein the drug is carried by the balloon as a platform.

62. (Previously Presented) A method as in claim 60, wherein releasing comprises embedding the drug through the stenotic material into the vessel wall.

63. (Previously Presented) A method as in claim 62, wherein the drug is present in capsules.

64. (Previously Presented) A method as in claim 62, wherein the drug is present in a drug-containing polymer.

65.-68. (Canceled)

69. (Previously Presented) A method as in claim 60, wherein the metal scoring elements are included in a scoring cage slidably carried to the expansible balloon.

70. (Previously Presented) A method as in claim 60, wherein the scoring elements in the scoring cage are arranged helically over the expansible balloon.

**10. Evidence Appendix**

None.

**11. Related Proceedings Appendix**

None.

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